

FEB 04 2002

K012607  
Page 1 of 2



## 510(k) Summary of Safety and Effectiveness

**Submitter:** Alliance Medical Corporation  
10232 South 51<sup>st</sup> Street  
Phoenix, Arizona 85044

10232 South 51<sup>st</sup> Street  
Phoenix, Arizona 85044

TEL 480.763.5300  
FAX 480.763.5310  
Toll Free 888.888.3433  
www.alliance-medical.com

**Contact:** Don Selvey  
Vice President, Regulatory Affairs and Quality Assurance  
(480) 763-5300

**Date of preparation:** August 10, 2001

**Name of device:** Trade name: Alliance Medical Corporation  
Reprocessed Hot Biopsy Forceps

Common name: Hot Biopsy Forceps

Classification name: Endoscopic Electrosurgical Unit and Accessories

Manufacturer	Description	Models
Medinnovation Thermal		
Ballard Products	Option® II	60101, 60104, 60109, 60110, 60121, 60122
Boston Scientific	Microvase Radial Jaw®	
	3	1550

**Predicate Devices:**

K Number	Device Description	Procode
K932266	Symbiosis Disposable Gastro Biopsy Forceps	GEI
K910964	Symbiosis Hot Biopsy Forceps	GEI
K860366	Microvase Challenger Hot Biopsy Forceps	GEI
K932790	Thermal Option Electric Biopsy Forceps	KGE

**Device description:**

Biopsy forceps are specially designed instruments that can be used to collect tissue during an endoscopic procedure. Biopsy forceps have a flexible shaft that is designed for introduction through a compatible sized endoscopic operating channel. The instruments incorporate a handpiece with loop-shaped handles for opening and closing the collecting jaws.

Reprocessed biopsy forceps include non-electro-surgical (cold)

biopsy forceps without cauterizing function and electrosurgical (hot) biopsy forceps with cauterizing function. This 510(k) applies to electrosurgical (hot) biopsy forceps with cauterizing function.

**Intended use:** Reprocessed hot biopsy forceps are intended to be used endoscopically to obtain tissue specimens, remove polyps, and cauterize tissue.

**Indications statement:** Reprocessed hot biopsy forceps are indicated for use to collect tissue in patients requiring histological examination of the gastrointestinal tract, cauterizing of tissue and removal of polyps.

**Technological characteristics:** The intended use and technological features of the reprocessed devices do not differ from the legally marketed predicate device(s). Both the reprocessed device(s) and the predicate device(s) have the same materials and product design. The technological characteristics of the reprocessed hot biopsy forceps are the same as those of the legally marketed predicate devices.

Alliance Medical Corporation's reprocessing of hot biopsy forceps includes removal of adherent visible soil and decontamination. Hot biopsy forceps are tested for electrical continuity and for the ability of the jaws to grasp appropriately. Each individual instrument is tested for appropriate function prior to packaging, labeling, and sterilization operations.

**Performance data:** Performance data demonstrates that Reprocessed Hot Biopsy Forceps perform as originally intended.

**Conclusion:** In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Alliance Medical Corporation concludes that the modified device (Reprocessed Hot Biopsy Forceps) is safe, effective and substantially equivalent to the predicate devices as described herein.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB 04 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Don Selvey  
Vice President, Regulatory Affairs  
And Quality Assurance  
Alliance Medical Corporation  
10232 South 51<sup>st</sup> Street  
PHOENIX, ARIZONA 85044

Re: K012607

Trade/Device Name: Reprocessed Hot Biopsy Forceps  
Ballard 60101, 60104, 60109, 60110, 60121, 60122  
Microvasive 1550  
Regulation Number: 21CFR 876.4300  
Regulation Name: Endoscopic electrosurgical unit  
and accessories

Regulatory Class: II  
Product Code: 78 KGE  
Dated: November 9, 2001  
Received: November 15, 2001

Dear Mr. Selvey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

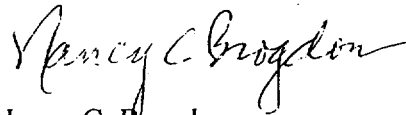
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

K012607  
Page 1 of 1

510(k) Number (if known):

Device Name: Alliance Medical Corporation Reprocessed Hot Biopsy Forceps

**Indications for Use:** Reprocessed Hot Biopsy Forceps are indicated for use to collect tissue in patients requiring histological examination of the gastrointestinal tract, cauterizing of tissue and removal of polyps.

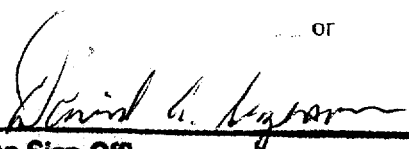
Manufacturer	Description	Models
Medinnovation Thermal		
Ballard Products	Option® II	60101, 60104, 60109, 60110, 60121, 60122
Boston Scientific	Microvasive Radial Jaw® 3	1550

Concurrence of CDRL, Office of Device Evaluation (ODE)

Prescription Use ☒  
(per 21 CFR 801.109)

or

Over-the-Counter Use ☐

  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K012607

CONFIDENTIAL

Alliance Medical Corporation  
Reprocessed Hot Biopsy Forceps  
Traditional 510(k)